Pesticide Registration (PR) Notice 98-2: Liquid Chemical Sterilant Products

Notice To: Manufacturers, Producers, Formulators, and Registrants of Pesticide Products

Attention: Persons Responsible for Registration of Antimicrobial Pesticides

Subject: Liquid Chemical Sterilant Products

This notice advises applicants/registrants of antimicrobial pesticide products of new FIFRA provisions for liquid chemical sterilant products that are intended for use on critical or semi-critical devices. As described in this notice, these products are no longer regulated as "pesticides" by the Environmental Protection Agency (EPA), but as "medical devices" under the regulatory authority of the Food and Drug Administration (FDA). The statutory change in authority was effective on August 3, 1996. EPA retains jurisdiction for liquid chemical sterilant products that are not intended for use on critical or semi-critical devices.

This notice informs registrants of liquid chemical sterilant products how to ensure that their products remain in compliance with FIFRA requirements where FIFRA still applies, and how products no longer regulated under FIFRA will be treated by EPA. The key provisions of this notice are as follows.

o Producers of liquid chemical sterilant products that are now solely under FDA jurisdiction should remove all EPA references such as the Registration No. and the Establishment No. from their labels.

o Registrants of products that bear mixed FDA- and EPA-regulated claims must "split" their product labels to include only EPA-regulated claims for their pesticide products, and should state only FDA-regulated claims for their medical devices.

o Registrants of products that are solely under EPA jurisdiction, and that comply with EPA requirements for general purpose disinfectants covered under PR Notice 94-4, are not required to take any action under this notice.

In order to remain in compliance with FIFRA, as soon as possible, but no later than 120 days after issuance of this notice, affected registrants with mixed FDA- and EPA-regulated claims must submit to EPA applications for amendment to delete FDA-regulated claims. The cutoff date for registrant sale or distribution of product currently labeled with both EPA- and FDA- regulated claims is October 1, 1998. There is no cutoff date for products that are in channels of trade as of October 1, 1998. However, EPA strongly encourages early submission of applications and relabeling of products to minimize the confusion of products with mixed FDA- and EPA- regulated claims in channels of trade.

I. WHAT PRODUCTS ARE AFFECTED?

This notice applies to products that are liquid chemical sterilants, intended for use on critical or semi-critical devices, and subordinate

disinfectant claims for critical or semi-critical devices such as tuberculocidal or virucidal claims which support a high level disinfectant use pattern. The terms "high level disinfectant" and "high level disinfection" are terms of art used by the public health community and are recognized by FDA as a separate or subcategory of sterilants. Accordingly, the terms "high level disinfectant" or "high level disinfection" will be used throughout this document in discussing FDA-regulated claims. For a discussion of these and other relevant terms used throughout this document refer to PR Notice 94-4.

This notice does not affect:

A. Products not bearing sterilant claims, regardless of use site.

B. Any gaseous chemical sterilant, such as ethylene oxide, regardless of use site and any other type of chemical sterilant that is distributed and sold in non-liquid form, even if in use it will be in liquid form.

C. Liquid chemical sterilants intended solely for use on surfaces other than critical or semi-critical devices, e.g., environmental surfaces or manufacturing and packaging processes. The terms critical and semi-critical devices are defined by FDA in terms of their use in or on the human body. Liquid chemical sterilants intended for sterilization of similar veterinary devices are regulated by EPA.

II. BACKGROUND

To address the concurrent jurisdiction of EPA and FDA over certain liquid chemical germicide products, a Memorandum of Understanding (MOU) between EPA and FDA was signed on June 4, 1993. The MOU was amended on June 20, 1994. The MOU (1) provides that EPA would undertake rulemaking to permanently vest exclusive jurisdiction for certain categories of liquid chemical germicides with FDA, and FDA would exempt certain categories of liquid chemical germicides from premarket clearance, and (2) serves as interim guidance to minimize duplicate regulatory requirements until the rulemaking is complete.

Under the MOU, each Agency was given lead responsibility over one of the two categories of liquid chemical germicides considered to be devices. FDA took primary responsibility over certain liquid chemical sterilants, which also included responsibility over high level disinfectant claims, such as subordinate tuberculocidal, virucidal, and fungicidal claims, associated with the use of these products on critical or semi-critical devices. EPA retained primary responsibility over the general purpose disinfectants.

On June 30, 1994, EPA issued PR Notice 94-4, which provided detailed guidance on interim EPA registration procedures for liquid chemical sterilants and general purpose disinfectant products affected by the June 4, 1993 MOU. Registrants were reminded that FDA approval of their products was needed. According to FDA, a product regulated by FDA that is not in compliance with FDA requirements may not be sold or distributed in interstate commerce.

III. FOOD QUALITY PROTECTION ACT OF 1996

Before either Agency was able to issue regulations under the MOU, the Food Quality Protection Act of 1996 (FQPA) was enacted. Among other things, this law amended section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA) to remove from the definition of "pesticide" liquid chemical sterilants for use on critical or semi-critical devices (and subordinate disinfectant claims on those products). The result is that such products and their affected claims are no longer regulated as pesticide products. The relevant portion of sec. 2(u) is as follows:

The term "pesticide" does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). For purposes of the preceding sentence, the term "critical device" includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term "semi-critical device" includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body."

This change in FIFRA vests exclusive jurisdiction for affected liquid chemical sterilants with FDA. EPA no longer needs to issue regulations to transfer authority, and will no longer follow the procedures described in the MOU with respect to these products. After these products no longer bear any EPA-regulated claims (as discussed in Section V), they will be subject solely to the regulatory and enforcement requirements of FDA. However, this does not affect enforcement or regulatory actions against affected products that are based upon actions that took place before August 3, 1996.

EPA retains jurisdiction for all pesticide uses of non-liquid chemical sterilants including ethylene oxide and for liquid chemical sterilants which bear claims for use on devices, surfaces, or objects other than critical or semi-critical devices. These products include, but are not limited to: sterilants used on veterinary instruments, environmental surfaces, and in manufacturing and packaging processes.

Registrants should note that, since there are no channels of trade date (see Section VII), existing stocks of products bearing mixed claims that are sold or distributed by the registrant on or before October 1, 1998, may remain in commerce after products have been "split" pursuant to this notice. EPA retains jurisdiction over a product as long as any EPA-regulated claim appears on the labeling.

The interim measures outlined in the MOU and PR Notice 94-4 relating to general purpose disinfectants remain in effect until FDA completes rulemaking to exempt these products from FDA premarket clearance requirements.

IV. POLICY

The following Agency policy pertains to all liquid chemical sterilant products for use on critical or semi-critical devices.

A. New products. EPA will not accept any application for registration of a liquid chemical sterilant which bears sterilant only or sterilant and subordinant disinfectant claims for use on critical or semi-critical devices. Persons who wish to market new products with such claims should contact the FDA Liaison Officer listed in Section X. If any applications

are currently pending with the Agency, EPA will administratively withdraw them as of the date of issuance of this notice without further notice to applicants.

B. Registered products with only FDA-regulated claims. As of August 3, 1996, registered products bearing only sterilant and subordinant disinfectant claims for use on critical or semi-critical devices, which are regulated by FDA, were no longer required to be, and are no longer considered to be, registered under FIFRA. EPA will administratively withdraw the registrations of such products effective as of the date of issuance of this notice. Registrants of these products are not required to request cancellation of registration for these products. Effective at the same time, EPA will also stop review of, and administratively withdraw, any pending actions for these registrations. If a registrant or producer intends to continue to market these products under FDA jurisdiction, he should remove all EPA references from the labeling, including the EPA Registration number and EPA establishment number (see Section V).

C. Registered products with mixed claims. A liquid chemical sterilant regulated by EPA under FIFRA may not bear mixed claims (that is, claims for both FDA-regulated critical or semi-critical devices, and general purpose disinfection or other use sites that are EPA-regulated). The registrant must modify the registration as described in Section V in order to remain in compliance with FIFRA.

V. RESPONSE TO THIS NOTICE

A. Products bearing mixed claims. A registrant whose liquid chemical sterilant product bears mixed claims for sterilant use, or sterilant and subordinant disinfectant claims on critical or semi-critical devices along with such claims on other sites, or general purpose or other uses, and who wishes to retain his product registration under FIFRA, must amend the product registration by deleting all claims for any use on critical or semi-critical devices. Because FIFRA has been modified, EPA is allowing an additional period of time to ensure that all EPA-regulated products are in compliance.

1. Because critical or semi-critical device use sites on pesticide labeling are not always explicit, i.e., the unqualified term "hard surface" may be interpreted by the user to include critical or semicritical devices, EPA must approve the proposed deletion. Therefore, a registrant may delete such claims only by amendment. Amendment by notification is not acceptable.

2. Submit(*1) an application for amended registration (EPA Form 8570-1), together with 2 copies of the current approved labeling, marked to indicate the critical or semi-critical device uses to be deleted. (Please do not simply highlight the marked text--highlighting does not photocopy). On the Application for Amendment, include in Section II, the statement: "Amendment to remove claims for use as a sterilant on critical or semi-critical devices per PR Notice 98-2."

(*1) The collection of information related to the registration of pesticide products has been approved by the Office of Management and Budget under the Paperwork Reduction Act under OMB Control Number 2070-0060. This approval expires May 31, 1998.

3. Submit applications for amendment as soon as possible, but no later than 120 days of issuance of this notice. Applications for deletion will be treated as "minor amendments," with a decision time of 90 days. Once new labels are approved, EPA encourages registrants to begin promptly to relabel products with the new labels, even though products may continue to be sold or distributed by the registrant under the old label until October 1, 1998.

B. Liquid chemical sterilants bearing EPA references. For any liquid chemical sterilant that was previously registered by EPA but now is regulated solely by FDA which currently bears an EPA Registration number and EPA establishment number, the producer should revise the label to delete all such EPA references. No submission to EPA is required for this purpose.

C. Registrants are reminded that they are responsible for ensuring that their (supplemental) distributor products comply with the FIFRA requirements described in this notice.

VI. ADDRESS FOR SUBMISSIONS

Applications should be sent to the following addresses:

By US mail:

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Courier Deliveries Monday - Friday, 8:00 AM to 4:30 PM
Excluding Holidays:

Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

VII. SALE OR DISTRIBUTION DATE

The change of authority for liquid chemical sterilants for use on critical or semi-critical devices from mutual EPA and FDA authority to exclusive FDA authority is the result of changes in FIFRA. EPA's purpose in providing this guidance is to accomplish the transition in an orderly fashion without undue disruption in the marketing or use of these products.

EPA recognizes a need to minimize confusion in the user community caused by this transition. Therefore EPA is establishing a final date after which registrants may no longer distribute or sell non-complying product into commerce. PR Notice 94-4 established a registrant compliance date of October 1, 1995. In light of the FIFRA revision, EPA is extending the registrant compliance date until October 1, 1998.

Liquid chemical sterilants with both approved FDA labeling and approved EPA labeling will be in compliance with FIFRA until October 1, 1998, except that this notice does not authorize distribution or sale of a product that currently may not be distributed or sold because of an existing EPA enforcement or regulatory action.

EPA sees no reason to require that product already in commerce be recalled or relabeled. Therefore, EPA is eliminating the October 1, 1997 channels of trade date established by PR Notice 94-4.

Accordingly the following dates apply:

☐After approval of amendment (but no later than October 1, 1998). A registrant may begin to sell or distribute an EPA-registered product that has been amended to delete FDA-regulated claims as soon as EPA has approved the deletion.

☐After October 1, 1998:

1. An FDA-regulated liquid chemical sterilant for use on critical or semi-critical devices should comply only with FDA requirements. The label should not bear any EPA references, such as an EPA Registration Number or establishment number.

2. A registrant may not distribute or sell an EPA-registered product bearing FDA-regulated sterilant claims (or subordinant disinfectant claims). Such a product may be deemed to be misbranded under FIFRA.

3. Registrants must maintain a sales inventory of their products with mixed labeling claims to verify that products bearing mixed labeling claims in channels of trade after October 1, 1998 were distributed or sold on or before October 1, 1998.

VIII. PR NOTICE 94-4

A. Liquid Chemical Sterilants For Use On Critical or Semi-critical Devices. This notice supersedes all provisions of PR Notice 94-4 with respect to liquid chemical sterilants. Section IV of that notice contained procedures for EPA registration of liquid chemical sterilants for use on critical or semi-critical devices. Section VI of that notice stated that FDA package inserts for liquid chemical sterilants for use on critical or semi-critical devices were required to meet EPA labeling requirements. Those requirements no longer apply. Refer to PR Notice 94-4 for a discussion of these requirements.

B. General Purpose Disinfectants. The provisions of PR Notice 94-4 that apply solely to general purpose disinfectants continue to apply. Moreoever, PR Notice 94-4 applies to products that become general purpose disinfectants by deleting FDA-regulated sterilant claims for use on critical or semi-critical devices. Sections V and VI of that notice required labeling statements prohibiting use as a sterilant. Registrants were required to amend their labels to include this limitation and begin distributing and selling newly-labeled product no later than October 1995. EPA believes that all products now entering channels of trade bear this limitation. This limitation is and will continue to be in effect for all EPA-regulated products with label directions for pre-cleaning critical or semi-critical devices.

Section VI of PR Notice 94-4 required that, as of October 1997, any general purpose disinfectant that is registered for any medical device or medical equipment surface claim bear the limitation that the product is not to be used as a terminal sterilant/high level disinfectant for critical or semi-critical medical devices. This notice eliminates that channels of trade date; however, all EPA-regulated products with label directions for pre-cleaning critical or semi-critical devices must continue to bear this limitation.

IX. STATE REGULATION

Although liquid chemical sterilants (and subordinant disinfectant claims) on critical or semi-critical devices have been removed from EPA jurisdiction under FIFRA, many States continue to regulate these products as pesticides. The authority of the States to regulate such liquid chemical sterilant products may not have been affected by the change in FIFRA. Companies should consult with individual States to determine the regulatory status of their liquid chemical sterilant products under State law.

X. FOR FURTHER INFORMATION

If you do not understand this notice, or what you should do to comply, please contact one of the following people:

At the Environmental Protection Agency:

Michele E. Wingfield
Office of Pesticide Programs
Antimicrobials Division (7510W)
401 M Street, S.W.
Washington, D.C. 20460

Phone: (703) 308-6349
E-mail: wingfield.michele@epamail.epa.gov

At the Food and Drug Administration:

Dr. Chiu S. Lin
Center for Devices and Radiological Health (HFZ-480)
Food and Drug Administration
9200 Corporate Boulevard,
Rockville, MD 20850

Phone: (301) 443-8913
E-mail: cxl@fdadr.cdrh.fda.gov

Frank T. Sanders, Director
Antimicrobials Division
Office of Pesticide Programs